REMARKS

Applicants would like to thank the Examiner for the comments in the Office Action mailed May 26, 2009.

Applicants have amended claim 1 to incorporate the features of 'a lower barrel (30) at the end remote from the upper barrel which comprises a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body, a sliding piston (48) and a means (22) for slidably receiving a packaged drug (100) configured such that a packaged drug attached thereto can slide within the device and act against said piston in the device to prime it'.

Basis for this amendment comes from original claims 2, 3, 6 and 20.

Additional basis may be found in the specification at page 12, paragraph 3: '*...the device can't be primed until the packaged drug is attached thereto since it is the packaged drug that acts against the piston in the device to cause the spring to be tensioned*'; page 14, paragraph 1: '*preferably the region for engaging the packaged drug to the drug delivery device in a slidable manner additionally comprises a means for positively locking it to the device such that it can still slide within the device...*' and page 20, paragraph 2: '*...the packaged drug slides up the lower chamber pushing the piston*'.

Applicants have also made minor amendments to claims 22, 34, 37 and 57 to better recite the invention in light of the prior art.

The Examiner has raised an objection to the drawings stating that they are generally informal and the reference characters are difficult to distinguish. Applicants have submitted with this Amendment replacement drawing sheets to overcome these objections. Reconsideration of the replacement drawing sheets is requested.

The Examiner has stated that the abstract should not exceed 150 words. Applicants have amended the Abstract to overcome this objection. Reconsideration of the amended Abstract is requested.

The Examiner has rejected claim 22 on the basis that it is difficult to understand. Applicants have made minor amendments to this claim to correct this deficiency and believe that these amendments are sufficient to overcome the rejection.

The Examiner has rejected claim 57 as being in improper form. Applicants have amended claim 57 and have also added new claim 58 in order to overcome this rejection. Applicants believe that this will overcome the Examiner's rejection.

The Examiner has raised a rejection against claim 57 on the basis that the method is not enabled when the packaged drug is used with any delivery device. Applicants have amended this claim to refer to a method of delivering the packaged drug when used with the claimed device and trust that this amendment will overcome the Examiner's rejection.

The Examiner has stated that claim 7 is indefinite. Applicants have amended this claim to refer to the housing as a 'two-piece housing' to differentiate this component from the housing of the device. Basis for this amendment can be found in paragraph [0131].

The Examiner has rejected claims 1-7, 9, 11-14, 16-19, 26-31, 34-38, 41-43, 45, 47 and 57 as being unpatentable over US2,398,544 (Lockhart).

While Applicants do not necessarily agree with the rejection, Applicants have amended claim 1 to include the feature of '*a sliding piston (48) and a means (22) for slidably receiving a packaged drug (100) configured such that a packaged drug attached thereto can slide within the device and act against said piston in the device to prime it*'. Claim 1 comprises the already recited limitation that the device is '*configured to push the drug from the packaging into the human or animal body at a velocity of less than 20m/s*'. None of these features are disclosed in Lockhart.

There are significant disadvantages to the liquid jet injector of Lockhart which are not apparent from the disclosure: The outer layers of the skin are the most difficult to penetrate. If the liquid jet is not traveling at a sufficiently high velocity it will just splash-back off the skin. Once the outer layers of the skin have been penetrated, and if the liquid continues at the same high velocity, there is a danger of significant damage being done to the tissue causing bruising and bleeding to the recipient. Skin thickness varies across the human body between the standard injection sites of the upper arm, abdomen and thigh making it very difficult to set up a liquid jet injector for a single individual.

The skin thickness between differently aged people (children vs. adults vs. geriatrics) and different ethnic backgrounds (Caucasian vs. Asian vs. Black African etc) are even more marked making it more difficult to develop a standard jet injector. If the velocity of the liquid is not high

enough, variable dosing and splash-back are major concerns and splash-back can also be a significant source of cross-infection as acknowledged by the World Health Organization.

Further, problems occur if the discharge orifice is blocked or placed firmly on the skin because, as the injector is operated the liquid is pressurized but has no kinetic energy and is unable to pierce the skin. However, as soon as the injector is moved the jet may fire leading to accidental or a failed injection, for example, wherein relative movement between the epidermis and orifice causes tearing of the epidermis. Thus, the jet injector system is unsuitable for delivery of drugs characterized as being lipophilic, solid, hydrophobic or water insoluble that may block the jet injector or be too viscous for successful jet injection. As a result, the Lockhart needleless jet injector is limited in its application.

The present invention overcomes these substantial technical problems. In this case the device is configured in such a way that an injectate is pushed at a low velocity, for example in the manner of a splinter, rather than accelerated and fired as in Lockhart. Because the injectate is pushed at such a low velocity it would neither penetrate the skin without the pushing force behind it nor continue into the skin without the continued pushing force. Further, the injectate is so light (just a few milligrams) and going at such a low velocity that it does not have sufficient momentum (mass x velocity) to penetrate skin without the continuous pushing force of the device behind it. The injectate is pushed with sufficient force that it will penetrate any skin type or location on the body, thus overcoming a significant technical problem of the Lockhart device.

Surprisingly, there are a number of other technical effects associated with pushing a drug at low velocity and this solution leads to unexpected gains in the efficiency and breadth of application of the device.

The Lockhart device can only deliver liquid injections; however, the configuration of the present invention enables medicaments to be introduced in a wide variety of forms including drug splinters and rods or as injectates comprising pioneer projectiles followed by liquids, gels and pastes, etc.

While the Lockhart injector is limited to injection of drugs dissolved in relatively large volumes of liquid, the device of the present invention is capable of delivering drugs in a low volume form as small as, for example, a splinter. This significantly reduces the pain and duration of an injection limiting any bruising and avoiding any splash back, seepage or contamination.

The use of a low velocity further allows enhanced control over the injection with surprising gains in both accuracy and depth of injection. The device of the present invention will reproducibly deliver a medicament to the same depth of injection regardless of skin type or bodily composition. This is simply not possible with the Lockhart device wherein substantial variation in the depth of jet penetration exists for skin from different anatomic locations.

The ampoules of Lockhart are attached to the device by a collar which screws onto the housing. Contrary to the Examiner's comments, this means that the ampoule is fixed and cannot move or slide within the device.

The Lockhart device is cocked (i.e. primed) before an ampoule of medicament is positioned within the device – see for example Column 2, lines 61 to 69 – and as a result it is possible for the device to fire unexpectedly either before or as the ampoule is attached to the device. As a result and due to the high pressures involved, from 800 up to 10,000 pounds per square inch, significant accidental injuries may occur.

The claimed device of the present invention can only be primed and/or actuated when a packaged drug is positioned in the housing of the device. The packaged drug slides within the device and acts against a piston to allow the device to be primed/actuated. Thus, in the absence of such a packaged drug, and until such a packaged drug is attached, the device can neither be primed nor actuated.

The problems of Lockhart are thus overcome by the present invention, the features of which are neither taught nor suggested by Lockhart, leading to a great increase in safety.

The Examiner has stated that it would have been obvious to one skilled in the art to choose operating parameters wherein the velocity of the drug is less than 20m/s. Applicants respectfully disagree.

Lockhart does not teach or suggest any disadvantages to the use of high velocity needleless liquid jet injectors. Therefore one skilled in the art would not be motivated to adapt the Lockhart device and investigate low velocity drug delivery with any expectation of success. The skilled person could not simply reduce the velocity of administration to try to overcome the problems described above because this would lead to complete failure to deliver the liquid drug. Rather, they would be motivated to increase the velocity to force the liquid out of the device.

Hence, the significant advantages of the configuration of the present invention to push a drug at low velocity coupled with the associated safety features would be surprising and unexpected to one skilled in the art. For these reasons it is submitted that the claims are both novel and inventive over the disclosures of U.S. Patent No. 2,398,544 (Lockhart).

The Examiner has rejected claims 8, 32, 33, 39, 40, 46 and 48-52 as being unpatentable over Lockhart in view of U.S. Patent No. 4,968,302 (Schluter).

It is submitted that the shortcomings of Lockhart are not overcome by Schluter. Schluter discloses an injection device which utilizes a needle for high-speed discharge of a medicament. Such a device has none of the benefits described above relating to 'pushing' of a drug at a velocity of less than 20m/s. In addition, with the device of Schluter there again exists the possibility of accidental discharge.

In U.S. Patent No. 2,398,544, Lockhart refers to his co-pending application, now U.S. Patent No. 2,380,534. In this document Lockhart specifically states that the aim of developing the hypodermic injectors is '*to eliminate the necessity of using a hollow needle and the usual type of syringe in conjunction therewith*' (page 2, lines 10-15). Lockhart later states that such devices '*eliminate the risk of infection, fright, pain, etc. of the usual hypodermic needle*' (page 2, lines 30-35).

Thus, for these reasons Applicants believe that there is no motivation to combine these two documents and even if one was to combine the teachings, the deficiencies of both Lockhart and Schluter would not be overcome.

Favorable consideration and allowance of this application is respectfully requested.

Applicants believe there are no fees due for this document, however, if any fees are due, the Patent Office is authorized to charge or refund any fee deficiency or excess to Deposit Account No. 04-1061 in the name of Dickinson Wright PLLC.

Respectfully Submitted,

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